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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,852	09/30/2003	Jacqueline E. Heard	MBI-0022CIP	1145

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EXAMINER	
KRUSE, DAVID H	
ART UNIT	PAPER NUMBER
1638	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/675,852	HEARD ET AL.	
	Examiner	Art Unit	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *62-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *62-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

STATUS OF THE APPLICATION

1. This Office action is in response for the Amendment and Remarks filed on 15 April 2010.

2. Those rejections not specifically addressed in this Office action are now moot in view of Applicants' amendments to the claims.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicants' response has been fully considered (pages 5-7 of the Remarks). Applicants' evidence supports their claim of priority to U.S. Provisional Application 60/166,228 filed on 17 November 1999. See the document filed 15 April 2010 titled "Summary of Overexpressor G482, Family CATT". Applicants' assertion that there is sufficient written description support in U.S. Provisional Application 60/125,814 filed 23 March 1999 is not found to be persuasive (see page 2, last paragraph of the Office action mailed 15 October 2009).

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 62-77 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over pending claim 105 of copending Application No. 11/069,255 for the reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants arguments are noted (page 16, items 4-5 of the Remarks), but as the instant claims are not yet deemed allowable the instant rejection is maintained.

6. Claims 62-77 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over pending claims 68-75 of copending Application No. 10/286,264. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant SEQ ID NO: 4 is identical to SEQ ID NO: 14 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants arguments are noted (page 16, items 4-5 of the Remarks), but as the instant claims are not yet deemed allowable the instant rejection is maintained.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 62-64, 67-71 and 74-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a transgenic seedling or more mature plant comprising a recombinant polynucleotide encoding a polypeptide that specifically hybridizes to SEQ ID NO: 3 or the complement thereof under recited stringent conditions or the

polypeptide is at least 85-95% identical to SEQ ID NO: 4; and a method of making same.

Applicants describe a transgenic plant comprising a recombinant polynucleotide encoding instant SEQ ID NO: 4 operably lined to a constitutive CaMV 35S promoter that are more tolerant to high NaCl (salt) in a germination assay than an equivalent non-transformed plant (see Table 6, page 95 of the instant Specification).

Applicants do not describe recombinant polynucleotides or plants transformed therewith, that confer tolerance to salt or osmotic stress that hybridize to SEQ ID NO: 3 or the complement thereof under stringent conditions that comprise wash conditions of 0.2x SSC, 0.1% SDS at 65°C, or that encodes a polypeptide that is at least 85-95% identical to SEQ ID NO: 4.

Hence, it is unclear that Applicants were in possession of the invention as broadly claimed. It was recognized in Swindell et al. (2007) "The biological limitations of transcriptomics in elucidating stress and stress responses." *Heredity* 99: 143-150, that "[c]andidate genes *with a well-supported role in stress-response pathways* provide good prospects for subsequent experimental study" *(emphasis* added; page 149, left column), but "[t]he identification of temperature-related genes [i.e., regulated in response to environmental changes] through microarray analysis represents *only a first step* towards understanding their role in cold- and heat-stress- regulatory *pathways"(emphasis* added; page 149, left column). Given the nature of the art of the instantly claimed invention, Applicants' burden to show possession of the invention as broadly claimed

would be substantial given what those skilled in the art would view as being in Applicants' possession based on the description of the claimed invention.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 62-77 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Edwards *et al* (July 1998, Plant Physiology 117: 1015-1022) in view of Harada *et al* (U.S. Patent 6,235,975 B1, filed 24 June 1998) and in further view of Edwards (16 September 1997, Accession No. Y13724, Genbank Sequence, NCBI, National Library of Medicine, National Institutes of Health, Bethesda, MD). This rejection is repeated for the reason of record as set forth in the last Office action mailed 15 October 2009. Applicant's arguments filed 15 April 2010 have been fully considered but they are not persuasive.

Edwards teaches a recombinant polynucleotide encoding the AtHAP3b CAAT-box transcription factor having 874 nucleotides identical to that of Applicant's SEQ ID NO: 3, encoding 188 of 190 amino acids of Applicant's SEQ ID NO: 2. The AtHAP3b CAAT-box transcription factor taught by Edwards as the "conserved domain" of Applicants' SEQ ID NO: 4. Edwards teaches that expression of the AtHAP3b CAAT-box transcription factor in leaves from plants grown in soil but not in those from liquid culture may suggest environmental regulation of this gene, perhaps in relation to osmotic stress

(page 1021, left column, 2nd paragraph). Edwards teaches that further research is required to understand the regulation of this factor and its role in developmental and environmental responses. Edwards 1997 is cited as evidence that the AtHAP3b, CCAAT box binding protein as publicly disclosed on 16 September 1997.

Edwards does not specifically teach a transgenic plant comprising said recombinant polynucleotide.

Harada teaches that at the time of Applicant's invention, it was obvious to transform plants with recombinant polynucleotides encoding CAAT-box transcription factors. Harada teaches a transgenic plant comprising a recombinant nucleotide sequence encoding a LEC1 polypeptide that comprises a CCAAT binding factor domain. Harada teaches that said recombinant nucleotide sequence can be operably linked to a constitutive promoter (claim 7), an inducible promoter (claim 9) or a tissue-specific promoter (claim 11). Harada teaches a method of transforming a plant by selecting a polynucleotide, inserting into an expression vector, introducing said vector into a plant or plant cell and selecting a transformed plant (see column 13, lines 49-58; columns 15-17; and column 20, last paragraph to column 21). Harada teaches that the transgenic plant can be a dicot, a monocot or a gymnosperm (column 21, lines 31-45).

The claims would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention, because it would have been obvious to isolate a polynucleotide encoding the complete AtHAP3B gene and transform a plant with the AtHAP3b CAAT-box transcription factor taught by Edwards. The invention as a whole is directed to a transgenic plant. The characteristic of abiotic stress tolerance would have

naturally flown from the use of the AtHAP3b CAAT-box transcription factor to transform a wild-type plant. In addition, Edwards teaches that the AtHAP3b CAAT-box transcription factor appears to be expressed in relation to osmotic stress and hence, would have motivated one of ordinary skill in the art to produce a transgenic plant. Hence, it would have been obvious to produce a transgenic plant and select said plant based on a greater tolerance to osmotic stress. Given the success of Harada in making a transgenic plant overexpressing the LEC1 CCAAT-box transcription factor, one of ordinary skill in the art would have had a reasonable expectation of success.

Applicants argue that Edwards 1998 does not provide a transgenic plant comprising the sequence (page 10, last paragraph of the Remarks). Applicants argue that the 1997 publication cited by the Office teaches a protein sequence, not the use of said sequence, much less the polynucleotide encoding the protein, or the expression or the ectopic expression of said sequence in a plant, Applicants are not claiming a sequence, but a transgenic plant (page 11, 3rd paragraph of the Remarks). These arguments are not found to be persuasive because the instant rejection addresses the issue of Obviousness under 35 U.S.C. 103(a), not anticipation.

Applicants' arguments concerning priority for the instant claimed invention is addressed above (page 11, 4th paragraph of the Remarks). Given Applicants' priority date of U.S. Provisional Application 60/166,228 filed on 17 November 1999, Edwards 1998 would qualify as prior art under 35 U.S.C. 102(b).

Applicants argue that Harada represents a *significant* teaching away from the instantly claimed invention, particularly in light of the amendments provided herein that

specify the transgenic plant of the instant invention is a *seedling or more mature plant* (page 12 of the Remarks). This argument is not found to be persuasive. Harada teaches that it was obvious to one of ordinary skill in the art at the time of Applicants' invention to transform plants with CAATT type transcription factors as whole, hence the Examiner as considered the "subject matter sought to be patented…as a whole" (page 12, 2nd paragraph of the Remarks). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that overexpression of a polypeptide in a plant can lead to different results, for example, a plant may be produced that has an advantageous phenotype, a deleterious phenotype (e.g., see above discussion re Harada teaching away from the instant plants and methods), or no discernable alteration of phenotype. Applicants argue that without making the plant, one skilled in the art cannot predict with total accuracy which outcome will occur. Or, in other words, the desired result does not necessarily flow from overexpression of the transgene or polypeptide. Applicants argue that The Federal Circuit has ruled that inherent anticipation cannot be "established by probabilities or possibilities, and that, [t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient". *In re Robertson,* 49 USPQ 2d, 1949, 1951 (Fed. Cir. 1999). The court stated that the burden falls on the Examiner to "provide a basis in fact why the allegedly inherent characteristic necessarily flows from the

teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. Inter. 1990) (emphasis in original) (page 13, 3rd paragraph of the Remarks). These arguments are not found to be persuasive. First, Harada's teachings of known pitfalls in the art are not a specific teaching away of the combination of the teachings of the prior art. Second, what Applicants' had reduced to practice would have been *prima face* obvious to those of ordinary skill in the art at the time of Applicants' invention. Edwards teaches that expression of the AtHAP3b CAAT-box transcription factor in leaves from plants grown in soil but not in those from liquid culture may suggest environmental regulation of this gene, perhaps in relation to osmotic stress (page 1021, left column, 2nd paragraph).

Applicants argue that given that the instantly claimed sequences *are not* Lecl-related proteins, as shown below, there is not a finite number of identified, predictable solutions made by combining Edwards and Harada for the purpose of reaching the instant claims (page 15 of the Remarks). Again one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In the instant case Edwards teaches the subcombination (the tHAP3b CAAT-box transcription factor) and its apparent function and Harada teaches the level of skill in the pertinent art at the time of Applicants' invention to make transgenic plants.

Applicants argue that a publish sequence does not make an entire gene/protein family obvious (pages 15-16 of the Remarks). This is not found to be persuasive because an obvious species can render obvious a genus.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
6 July 2010